

Application No. 10/630,478
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Reply to Office Action of August 10, 2005

REMARKS/ARGUMENTS

1. Remarks on the Amendments

Claims 1-5, 8, 12-13, 17 and 19-21 have been amended to more specifically define Applicants' claimed invention.

Claims 6-7, 18 and 22 have been canceled, as they have been incorporated into the above-mentioned amended claims.

Antecedent basis for the amendment can be found in the claims and the Specification as filed. More specifically, antecedent basis for the amendment of Claim 1 step (g) can be found on page 16, last paragraph. Antecedent basis for Claim 1 step (b) can be found in Claim 21 as filed. Antecedent basis for Claim 12 step (b) can be found on page 15, lines 7-17 of the Specification as filed. Antecedent basis for the amendment of Claim 21 element (d) can be found on page 11, line 9-10 of the Specification as filed. Applicants respectfully submit no new matter has been introduced by the amendments.

2. Response to the Rejection of Claims 1-20 Based Upon 35 U.S.C. §103(a)

Claims 1-5, 8-17 and 19-20, stand rejected under 35 USC §103(a) as being unpatentable over Porter et al (US Patent No. 6,887,077). This rejection is respectfully traversed by the amendment.

Claims 1 and 12 are independent claims, and Claims 2-5, 8, and 13-17 and 19-20 are dependent claims of Claims 1 and 12, respectively.

A determination under 35 U.S.C. §103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. *In re Mayne*, 104 F.3d 1339, 1341, 41 USPQ 2d 1451, 1453 (Fed. Cir. 1997). An obviousness determination is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and prior art; and (4)

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the objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), see also *Robotic Vision Sys., Inc. v. View Eng'g Inc.*, 189 F.3d 1370 1376, 51 USPQ 2d 1948, 1953 (Fed. Cir. 1999).

In line with this standard, case law provides that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). The first requirement is that a showing of a suggestion, teaching or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175, F.3d 994, 1000, 50 USPQ 2d 1614, 1617. The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992).

The examiner has the burden of establishing a prima facie case of obviousness. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995). The burden to rebut a rejection of obviousness does not arise until a prima facie case has been established. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Only if the burden of the establishing prima facie case is met does the burden of coming forward with rebuttal argument or evidence shift to the application. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ 2d 1210, 1214 (Fed. Cir. 1995), see also *Ex parte Obukowicz*, 27 USPQ 2d 1063, 1065 (B.P.A.I. 1992).

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Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in amended Claims 1 and 12. More specifically, in regard to the amended Claim 1, Applicants' claimed method of expansion of bone tissue for receiving a dental implant requires creating a small initial osseotomy site; and providing multiple threaded expanders of substantially same structure with increasing diameters, each of the threaded expanders comprising: a top enabling engagement with a dental ratchet; a cylindrical shaft having a upper and a lower end, having depth markings along a longitudinal axis of the shaft; and a threaded expansion tip connected to the lower end of the cylindrical shaft; the threaded expansion tip of each of the multiple threaded expanders having a same length and a substantially same threaded structure to a threaded structure of the dental implant, yet a narrower outer diameter than the outer diameter of the dental implant; and screwing two or more of the threaded expanders consecutively into the osseotomy site, to expand the osseotomy site laterally and to obtain an expanded osseotomy site that has a complementary geometry to said dental implant, but grooves and threads on an interior wall of said expanded osseotomy site are uniformly narrower than outer diameters of complementary elements of the dental implant so that the expanded osseotomy site enables the implant to sufficiently bite into and uniformly engage with surrounding bone tissues.

Porter et al fail to teach the above recited method steps of Applicants' claimed invention, the functions provided by the structures of the instant threaded expanders and the method of use, and the objectives achieved by using Applicants' claimed method.

Applicants respectfully point out that Porter et al teach away from Applicant's claimed method, because Porter et al teach that after drilling a pilot hole (70) using one, or a series of, shaping drill (30) to create a larger bore having a cylindrical portion (72) and a tapered portion (73) by removing bone tissues, prior to applying their compression tap (50) (Column 5, lines 1-3 and 26-43, Column 4, lines 53-55, and Column 3, lines 38-65 of the reference). Porter et al specifically teach that the tapered portion (34) of the shaping drill (30) mimics the minor diameter of the tapered

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section (18) of the implant (10) (Column 3, lines 57-65). Porter et al. use their compression tap only to cause female thread in the bore. Therefore, the grooves and threads on an interior wall of the bore created by Porter et al's method are not uniformly narrower than outer diameters of complementary elements of the dental implant. This is substantially different from Applicants' claimed method which only uses drilling to create a small initial osseotomy site which has a diameter substantially smaller than the outer diameter of the dental implant, and then, relies on the expanders to expand radially to increase the bone density around the osseotomy site and to provide an expended osseotomy site in which grooves and threads on an interior wall of said expanded osseotomy site are uniformly narrower than outer diameters of complementary elements of the dental implant. The osseotomy site obtained using Applicants' claimed method enables the implant to sufficiently bite into and uniformly engage with surrounding bone issues which have an increased and substantially uniform bone density. As shown in Fig. 2 of the instant Specification, the pilot drill used in Applicant's claimed invention has no structural correlation to the dental implant. On the contrary, Applicants' claimed method requires each of the threaded expanders having a substantially same threaded structure to the threaded structure of the dental implant, with lesser diameters. The advantages achieved by Applicants' claimed method have been clearly stated in the instant application, a relevant section in the paragraph bridging pages 16 and 17 is recited below:

Different from the implant site prepared by osteotomes and threaded expanders of the known prior art, the bone density of the interior wall of the osseotomy site is uniform including the complementary grooves and threads. Further, and importantly the instant method provides a final diameter of the osseotomy site narrower than the outer diameter of the implant to be placed. This means that all grooves and threads embedded on the interior wall along the longitudinal axis of the osseotomy site are uniformly narrower than those complementary elements of the implant. Such an implant site

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allows the implant to sufficiently and uniformly bite into and engage uniformly with the surrounding bone tissue. It will be well appreciated by those skilled in the art that such a complementary structure of the implant site and the uniform engagement arrangement can provide an optimal support to the implant. Accordingly, the method of the present invention, superior to the known techniques, can lead to a further improvement of implant stability and an enhancement of subsequent osteointegration (emphasis added).

In an alternative approach, Porter et al teach to use conventional compression-type osteotome tools, prior to using their compression tap (50). As specifically stated in the instant application, Applicants' claimed invention is made to specifically avoid using these conventional compression-type osteotome tools because of various disadvantages associated with these tools.

It is apparent that Porter et al's method requires substantial expansions by either the shaping drill or by conventional compression-type osteotome, prior to applying the specific compression tap (50). Porter et al's methods either remove more bone tissues and lead to lesser bone density around the site when the shaping drill is used, or inhere the problems of the conventional compression-type osteotomes.

Based on Porter et al's opposite teachings, one skilled in the art would not be motivated to try to obtain Applicants' claimed invention, in the manner suggested by the Examiner. Therefore, Applicants maintain that Applicants' claimed invention defined by Claim 1 is not obvious in view of the art of the record.

In regard to the amended Claim 12, other than the similar steps defined in Claim 1, Applicants' claimed method requires drilling to extend the osseotomy site only at a cortical level to a diameter complementary to the outer diameter of the dental implant. This is to be used in the case of hard bone crest or placement of large dental implants. This additional step only extends the entrance of the initial osseotomy site at the cortical level, and the bone tissues of the initial osseotomy site underneath the cortical level are expanded and compressed by the threaded expanders.

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In this aspect, Porter et al again teach away from Applicants' claimed invention. More specifically, Porter et al fail to teach treating the cortical plate separately from other less dense bone tissues. On the contrary, Porter et al teach that using a series of the compression tap (50) to cause the female thread on the wall of the bore including the cortical level, which reduce the chance for fracture of the cortical plates in the region (Column 4, lines 60-64 of the reference).

In fact, the teaching of applying an additional step for handling hard cortical plate is completely absent in Porter et al's reference. One skilled in the art would be motivated to try to obtain Applicants' claimed invention based on the prior art teaching.

Therefore, Applicants maintain that Applicants' claimed invention defined by Claim 12 is not obvious in view of the art of the record.

With regard to Claims 2-5, 8, and 13-17 and 19-20, as described above, these claims are dependent upon independent Claims 1 and 12. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claims 1 and 12 are unobvious in view of the prior art of record, as such Claims 2-5, 8, and 13-17 and 19-20 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection of Claims 1-5, 8-17 and 19-20 based upon 35 U.S.C. §103(a).

3. Response to the Rejections of Claim 11 Based Upon 35 U.S.C. §103(a)

Claim 11 stands rejected under 35 USC §103(a) as being unpatentable over Porter et al (US Patent No. 6,887,077) in view of Dalmau (6,146,138). This rejection is respectfully traversed.

Claim 11 is dependent upon independent Claim 1. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 1 is unobvious in view of the prior art of record, as such Claim 11 is submitted as being allowable over the art of record.

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Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 11 based upon 35 U.S.C. §103(a).

4. Response to the Rejections of Claims 21-24 Based Upon 35 U.S.C. §103(a)

Claims 21 and 23-24 stand rejected under 35 USC §103(a) as being unpatentable over Porter et al (US Patent No. 6,887,077) in view of Lorenzi (2002/0094508). This rejection is respectfully traversed by the amendment.

The applicable case law for a rejection under 35 U.S.C. §103 (a) has been discussed above in the response to the rejection of Claims 1-20 under 35 U.S.C. §103 (a). In the interests of brevity, Applicant requests the Examiner to note the above sections and consider that material incorporated herein by reference.

Applicant submits that nothing in the art of record teaches or suggests the subject matters positively recited in Claim 21. More specifically, Applicants' claimed kit of bone expanders comprises a plurality of threaded expanders of substantially same structure with increasing diameters, each of the expanders comprising a top enabling engagement with a dental ratchet; a cylindrical shaft having depth markings; a transition; and a threaded expansion tip having a substantially same threaded structure to a threaded structure of the dental implant, but a narrower outer diameter than an outer diameter of the dental implant; wherein the threaded expansion tip of each of the plurality of expanders has a same length.

Porter et al's method has been discussed above. Furthermore, in terms of the structure of the expanders, as recognized by the Examiner, Porter et al fail to teach Applicants' claimed top, shaft having depth markings and the transition. Moreover, Porter et al fail to teach Applicants' claimed kit wherein the threaded expansion tip of each of the plurality of expanders has a same length and a substantially same threaded structure to the threaded structure of the dental implant, but a narrower outer diameter than the outer diameter of the dental implant. It is important to understand that it is the combination of the same length of the threaded expansion tips and the depth markings, which enables the dentist to achieve sequential radial expansions of

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the osseotomy site using the instant expanders, and ensures the subsequent expander(s) reinforcing the thread pattern formed by the previous expander(s).

Porter et al's defects are not overcome by Lorenzi.

More specifically, Lorenzi fails to teach Applicants' claimed kit wherein the threaded expansion tip of each of the plurality of expanders has a same length, and a substantially same threaded structure to the threaded structure of the dental implant, but a narrower outer diameter than an outer diameter of the dental implant.

The teaching related to the structural relationship between their rotary osteotome and the implant is absent in Lorenzi's reference, because Lorenzi merely uses the rotary osteotome to widen the site, but does not intend to create a thread pattern in the osseotomy site for uniform engagement of the dental implant with the created thread pattern. Lorenzi's teaching is recited below:

[0034] After osteotome 36 is withdrawn from the implantation site, a next successively sized osteotome is employed to widen the site further, until the desired diameter (that is, a diameter corresponding to that of the implant cylinder) is obtained. Thereafter, the implantation site is further prepared as desired, such as by cutting threads in the interior surface of the implantation site, and the implant cylinder is inserted or threaded into the prepared implantation site. (emphasis added)

First, it is apparent that Lorenzi fails to teach Applicants' claimed kit wherein the threaded expansion tip of each of the plurality of expanders has narrower outer diameter than the outer diameter of the dental implant. Instead, Lorenzi teaches using his osteotome to obtain a diameter corresponding to that of the implant cylinder.

Second, Lorenzi teaches away from Applicant's claimed kit wherein the threaded expansion tip of each of the plurality of expanders has a substantially same threaded structure to the threaded structure of the dental implant. Because Lorenzi teaches to further prepare the expanded implantation site, particularly by cutting threads. After such a further preparation, the threads formed by the rotary

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osteotomes no longer exist. Therefore, there is no need for Lorenz's rotary osteotomes to have the same thread structure to the threaded structure of the dental implant.

Third, Lorenzi fails to teach Applicant's claimed kit wherein the threaded expansion tip of each of said plurality of expanders has a same length. As discussed above, it is the combination of the same length and the depth marking, which ensures the subsequent expander(s) reinforcing the thread pattern formed by the previous expander(s). As discussed immediately above, Lorenz does not rely on the thread pattern created by the osteotomes, therefore, there is no need for his osteotomes to reinforce the thread pattern one after the other.

Based on the prior art's teachings, one skilled in the art would not be motivated to combine the references, in the manner suggested by the Examiner, to obtain Applicants' claimed invention.

Therefore, Applicants maintain that Applicants' claimed invention defined by Claim 21 is not obvious in view of the art of the record.

With regard to Claims 23-24, as described above, these claims are dependent upon independent Claim 21. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 21 is unobvious in view of the prior art of record, as such Claims 23-24 are submitted as being allowable over the art of record.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 21 and 23-24 based upon 35 U.S.C. §103(a).

It is respectfully submitted that Claims 1-5, 8-17, 19-21 and 23-24, the pending claims, are now in condition for allowance and such action is respectfully requested.

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Applicants' Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

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